

**REMARKS**

Claims 1-3 and 21-26 are pending in this application. Claims 1-3 have been amended herein above. Claims 4-20 have been cancelled. Claims 21-26 are new.

Applicants acknowledge that claims 1-3 of this application have been rejected under the judicially created doctrine of obviousness-type double patenting based on U.S. Patent No. 6,252,045. Upon indication by the Examiner that the claims are allowable over the prior art, Applicants will submit a terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) to overcome the non-statutory double patenting ground provided by the Examiner.

The claims of this application stand rejected under 102(a) as being anticipated by "Interspecies Diversity of the Occludin Sequence: cDNA Cloning of Human, Mouse, Dog, and Rat-Kangaroo Homologues," Ando-Akatsuka et al., The Journal of Cell Biology, Vol. 133, No. 1, April 1996 43-47 (hereinafter referred to as the Ando-Akatsuka publication). The Examiner asserts that the effective filing date of the instant application is March 14, 1997 (the filing date of PCT/US97/05809).

Applicants respectfully disagree with the Examiner and submit that the present invention as currently claimed was not known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

It is respectfully submitted that the enclosed Declaration of Dr. Anderson, along with its accompanying Exhibits, provides facts that are sufficient to establish Applicants' reduction to practice of the presently claimed invention prior to the earliest effective date (i.e., the publication date) of the Ando-Akatsuka publication. Exhibit B to the Declaration of Dr. Anderson contains laboratory notebook pages dated prior to the earliest publication date of the Ando-Akatsuka publication demonstrate reduction to practice of the invention prior to the earliest publication date of the Ando-Akatsuka publication. However, the dates have been redacted to preserve the secrecy of the date of invention. Therefore, Applicants respectfully request that the §102(a) rejection of claims 1-3 be reconsidered and withdrawn.

The claims of the present application have been rejected under 35 U.S.C. 112, first paragraph. The Examiner asserts that the specification of the present application has insufficient written description to show that Applicants were in possession of a polypeptide that is 60%, 80%, or 90% identical to SEQ. ID. NO. 2.

The claims of the present application recite an isolated and purified human occludin polypeptide having at least about 60%, 80%, or 90% sequence homology with residues 33 to 522 of SEQ. ID. NO: 2. As presently claimed, each claimed polypeptide is active in inhibiting epithelial or endothelial barriers. The genera of proteins that must be variants of SEQ ID NO: 2 do not have substantial variation since all of the variants must possess the specified activity and must have respectively at least about 60%, 80%, or 90% identity to the reference sequence, SEQ ID NO: 2. The single species disclosed is representative of the

genera because (i) all members have, respectively, at least 60%, 80%, or 90% structural identity with the reference compound, and (ii) Applicants provided an assay for identifying all of the at least 60%, 80%, or 90% identical variants of SEQ ID NO: 2 that are capable of the specified catalytic activity. Thus, one of skill in the art would conclude that Applicants were in possession of the necessary common attributes possessed by the members of the genera. Therefore, Applicants respectfully submit that the disclosure meets the requirements of 35 U.S.C §112, first paragraph as providing adequate written description for the claimed invention.

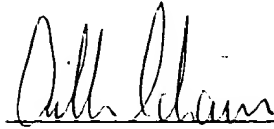
Applicants note that the foregoing analysis complies with the analysis provided by Example 14, Product by Function, Synopsis of Application of Written Description Guidelines, pp. 53-55, which is provided to Examiners by the United States Patent and Trademark Office.

In light of the foregoing, Applicants respectfully submit that the 35 U.S.C. §112, first paragraph, rejection of the present claims should be reconsidered and withdrawn.

Applicants respectfully request favorable consideration and that the claims of this application be passed to allowance.

If the Examiner has any questions regarding this response, he is requested to contact the undersigned at 203-575-2629 for a telephone interview prior to the issuance of the next office action.

Respectfully submitted,



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